

REMARKS

On an initial note, Applicants wish to thank the Examiner for withdrawing the previous final rejection. This Office Action Response is responsive to the Office Action dated September 12, 2006. Claims 1-20 are pending and Claims 1-20 currently stand rejected. Applicants have amended Claim 13 to correct a scribe's error. The Applicants submit that these minor amendments and corrections herein are made without prejudice as to patentability, including the doctrine of equivalents, and no new matter has been added.

Further, attached hereto is a request for a one-month extension along with a check in the amount of \$60. If any additional fees are required, the Commissioner is authorized to charge the fees to the deposit account of Bracewell & Giuliani LLP, Deposit Account No. 50-0259, attorney docket no. 044258.00002.

The Present Claimed Invention.

Embodiments of the invention advantageously provide a method of collecting fees for managing and optimizing profitability of physicians in a Healthcare Practice participating in an insurance network (open, out-patient environment) that is unique and operationally quite different than other systems and methods as set forth in the cited documents. Claimed embodiments, for example, include establishing a relationship between a Healthcare Consultation Group and the Healthcare Practice, modifying physician behavior with respect to ancillary medical costs responsive to the gathered data, distributing a percentage of savings if the Healthcare Consultation Group successfully modified the behavior, and/or paying funds from an incentive pool to the Healthcare Practice if the Healthcare Consultation Group failed to meet predetermined milestones.

Claim 1, for example, in part, features: establishing a relationship between a Healthcare Consultation Group and a Healthcare Practice to reduce a risk of the Healthcare Practice not receiving a predetermined reimbursement amount for ancillary medical costs from the insurance network; modifying behavior of at least one physician for management of the ancillary medical costs; paying funds from a funded incentive pool when the ancillary medical costs of the plurality of physicians in a Healthcare Practice do not decrease to a preselected level over a

preselected period of time; and distributing predetermined percentages of savings attributed to the modifying behavior. Claim 8, for example, in part, features: establishing a relationship between a Healthcare Consultation Group and a Healthcare Practice to reduce a risk of the Healthcare Practice not receiving a predetermined reimbursement amount for ancillary medical costs; establishing a plan to pay funds from the funded incentive pool when the ancillary medical costs of the plurality of physicians in the Healthcare Practice do not decrease to a preselected level over a preselected period of time; modifying behavior of at least one physician for management of the ancillary medical costs; and distributing predetermined percentages of savings attributed to the modifying behavior of the plurality of physicians ancillary medical cost management if the ancillary medical costs decrease to the preselected level over the preselected period of time. Claim 13, for example, in part, features: limiting a plurality of physicians' ancillary medical cost management behavior that is not preferred by the insurance network; modifying behavior of at least one physician for management of the ancillary medical costs; and distributing predetermined percentages of savings attributed to the modifying behavior of the plurality of physicians ancillary medical cost management to at least one of the insurance network and a healthcare management consultation group when the ancillary medical costs decrease to a preselected level over a preselected period of time.

Claims 1-20 are Nonobvious; No prima facie case.

The Examiner rejected Claims 1-20 under 35 U.S.C. § 103(a) as being unpatentable over Rosenstein (Changing Position Behavior Is a Tool to Reduce Health Care Costs) in view of Leet (U.S. Patent No. 6,000,828). Applicants respectfully disagree and traverse the rejection. Please note, because Applicants had difficulty understanding the Examiner's numbering scheme with respect to Rosenstein, Applicants have attached hereto a 5-page long copy of the Rosenstein reference including by-page paragraph numbering. Applicants referred to such attached copy in the following discussion as "Rosenstein" and the apparently 3-page long version cited by the Examiner as "Rosenstein (E)" which the Applicants did not have a copy of.

Rosenstein and Leet Each Fail To Recognize The Problems Addressed By Applicants' Claimed Invention.

As an initial matter, neither Rosenstein nor Leet recognize the specific source of the problem as identified, addressed and solved by embodiments of Applicants' claimed invention. As noted previously, the Supreme Court in the famous case of *Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45 (1923), has long acknowledged that recognition of a problem not previously recognized by others is part of the invention. *See also* MPEP 2141.02III ("[A] patentable invention may lie in the discovery of the source of a problem...."). Applicants' recognition of the source of the problem and methodology or solution to address and solve the particular problem in this case relates to gathering data on physician cost control risk or behavior, identifying those physicians at a greater risk, and behavior modification of physicians to reduce or control costs or expenses associated with such risk. Applicants submit that the recognition of the source and the unique solution provided by the embodiments of the Applicants' claimed invention is an indicator of nonobviousness of the invention.

As set forth extensively in the "Background" section of the instant Application, Applicants have recognized that previous methods of managing Healthcare Practice Groups have numerous disadvantages and have been largely unsuccessful in the climate and times of the instant application. For example, Applicants recognized that in healthcare practice group management, such as a plurality of physicians in a Healthcare Practice Group, managing the practice group effectively with respect to ancillary medical costs can be the difference between losing money and not. Applicants also recognized that the existing healthcare system will be difficult or impossible to overhaul. Applicants have also recognized a novel and nonobvious method of consulting with Healthcare Practice Groups to thereby reduce the risk that these groups lose money. As a result, those within the group, such as physicians, can more effectively manage their healthcare practice.

In particular and as indicated above, Claim 1, for example, provides a solution for optimizing profitability (controlling costs) for physicians in a Healthcare Practice participating in an insurance network (i.e., operating in an *open, out-patient* environment) by: (1) establishing a relationship between a Healthcare Consultation Group and the Healthcare Practice participating in the insurance network...; (2) funding an incentive pool; (3) gathering data in a tangible

computer medium from each of the plurality of physicians in the Healthcare Practice participating in the insurance network regarding management of ancillary medical costs; (4) modifying behavior of at least one of the plurality of physicians in the Healthcare Practice for management of the ancillary medical costs responsive to the data gathered in the tangible computer medium; (5) paying funds from the funded incentive pool to the Healthcare Practice participating in the insurance network when the ancillary medical costs of the plurality of physicians in the Healthcare Practice do not decrease to a preselected level over a preselected period of time; and (6) distributing predetermined percentages of savings attributed to the modifying behavior of the plurality of physicians ancillary medical cost management.

Claim 8, for example, provides a solution for optimizing profitability by: (1) establishing a relationship between a Healthcare Consultation Group and the Healthcare Practice participating in the insurance network...; (2) funding an incentive pool; (3) establishing a plan to pay funds from the funded incentive pool to the Healthcare Practice participating in the insurance network...when the ancillary medical costs of the plurality of physicians in the Healthcare Practice do not decrease to a preselected level over a preselected period of time; (4) gathering data in a tangible computer medium from each of the plurality of physicians in the Healthcare Practice participating in the insurance network regarding management of ancillary medical costs; (5) modifying behavior of at least one of the plurality of physicians in the Healthcare Practice for management of the ancillary medical costs responsive to the data gathered in the tangible computer medium; and (6) distributing predetermined percentages of savings attributed to the modifying behavior of the plurality of physicians ancillary medical cost management if the ancillary medical costs decrease to the preselected level over the preselected period of time.

Claim 13, for example, provides a solution for optimizing profitability by: (1) establishing a relationship between a Healthcare Management Consultation Group and the Healthcare Practice participating in the insurance network...; (2) gathering data in a tangible computer medium from each of the plurality of physicians in the Healthcare Practice participating in the insurance network regarding management of ancillary medical costs; (3) modifying behavior of at least one of the plurality of physicians in the Healthcare Practice for management of the ancillary medical costs responsive to the data gathered in a tangible computer medium; and (4) distributing predetermined percentages of savings attributed to the modifying

behavior of the plurality of physicians ancillary medical cost management to at least one of the insurance network and the Healthcare Management Consultation Group when the ancillary medical costs decrease to a preselected level over a preselected period of time.

In contrast, Rosenstein describes various strategies that administrators in a *closed, in-patient* (hospital) system will be looking at to reduce health care costs. *See* Rosenstein, page 1, para. 1 and page 4, para. 5 (stating that "[i]f a hospital closes, the physicians would be forced to find a new workshop for *inpatient* care..."). Rosenstein does not deal with *open, out-patient* systems, much less the detailed elements of the claims such as, for example, the steps of establishing a relationship with a Healthcare Consultation Group; funding an incentive pool; paying funds from a funded incentive pool to the Healthcare Practice...when ancillary medical costs...do not decrease to a preselected level over a preselected time period; or distributing predetermined percentages of savings to the physicians, Healthcare Practice Group, and/or insurance network, attributed to the modified physician ancillary medical cost management behavior. As will be described later, there are also numerous other features not mentioned in Rosenstein that are featured in the claims.

Nor does Leet provide such disclosure. Leet instead provides a methodology of determining what drug or combination may be the best to use on a specific treatment for a specific populace. *See* Leet, col. 2, lines 47-49 and col. 3, lines 15-24.

Neither Rosenstein nor Leet are reasonably pertinent to the particular problems with which Applicants were concerned. Applicants have clearly provided a unique methodology or solution to these problems. The specific recognition of the source of the Applicants' problems and unique methodology/solution are not found in the cited documents, alone or in combination. Therefore, persons of ordinary skill in the art who would endeavor to solve the problems recognized by Applicants would *not* seek out the cited documents, which both alone or in combination, fail to recognize the problems solved by the Applicants' claimed methodology. For this reason alone, Claims 1-20 define over the cited documents.

No Proper Prima Facie Case of Obviousness Has Been Set Forth As Required.

To establish a proper prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the

knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on the Applicants' disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); *see also* MPEP 706.02(J). The Applicants respectfully submit that the Examiner has not factually supported each element of the *prima facie* case of obviousness, and therefore, has not set forth a proper *prima facie* case.

No Suggestion or Motivation to Modify or Combine Reference Teachings.

Applicants respectfully submit that the Examiner has failed to meet the first element of a *prima facie* case for obviousness. First, there is no explicit suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. The Examiner has the burden of showing, as such, and has not met it here. Nor is there anything implicit suggesting combining the references, as the combined teachings, knowledge of one of ordinary skill in the art, and nature of the problem to be solved, as a whole, would not suggest doing so to those of ordinary skill in the art, as is required in MPEP 2143.01 and *In re Kotzab*, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000).

Neither Rosenstein nor Leet are directed to a system or method of collecting fees for managing a plurality of physicians in a Healthcare Practice participating in an insurance network to enhance or optimize profitability of the Healthcare Practice by modifying physician behavior with respect to ancillary medical costs. In fact, Rosenstein and Leet are different to the point of being non-analogous references. For example, as described previously, Rosenstein as a whole describes strategies hospital administrators can employ to reduce healthcare costs. Leet as a whole describes a methodology of improving drug effectiveness for a specific treatment for a specific populace by determining emerging patterns of microbial drug resistance in a community and altering patterns of antimicrobial prescribing to reduce, and thus, solve the problem of microbial evolutionary pressures that produce resistant organisms. Embodiments of Applicants claimed invention as a whole describe methods of and systems of collecting fees and enhancing

or otherwise optimizing profitability of a Healthcare Practice and/or managing physicians thereof with respect to ancillary medical costs.

Additionally, both Rosenstein and Leet apply only to hospitals or closed healthcare systems, where the claimed embodiments of Applicants invention apply to outpatient care or open healthcare systems. *See* Rosenstein, page 2, para. 3 (summarizing the content of the article), and Leet, Fig. 2, title, and col. 18, lines 26-48 (describing implementation of the Leet computerized medical record system). This is an important distinction because closed healthcare systems have different procedures, authorization, management, and record-keeping requirements.

Thus, the combined teachings, knowledge of one of ordinary skill in the art, and nature of the problems to be solved, as a whole (enhancing fee collection and profitability of a Healthcare Practice participating in an insurance network), do not suggest combining these disparate references, as the combination would not solve the Applicants' problems.

Second, even if the references somehow could be combined or modified, this still is not sufficient to establish a *prima facie* obviousness unless the cited documents also suggest the desirability of the combination. *See* MPEP 2143.01. In the present case, there is no suggestion as to the desirability of the combination. One must keep in mind that Rosenstein is an article discussing strategies hospital administrators (closed, in-patient system administrators) can employ to reduce healthcare costs, rather than on solving open, out-patient healthcare practice fee collection and profitability issues. *See* Rosenstein, page 2, para. 7. Leet provides a tool that can be used to recommend drug treatments which are allowed to evolve in response to changing medical information, side effects encountered, and patterns of disease resistance, to thereby recommended treatments; evaluate drug treatments to help improve drug treatments in the community in which the treatment is being provided; detect emerging patterns of microbial drug resistance in a community; and alter patterns of antimicrobial prescribing to reduce microbial evolutionary pressures that produce resistant organisms. *See* Leet, col. 3, lines 10-25.

Third, the Examiner's statements alone, that it would have been obvious to incorporate a computer tangible medium into the system of Rosenstein, is insufficient to establish a *prima facie* case of obviousness, even assuming the combination would actually solve the Applicants' problems (which it would not). Even assuming a motivation and an ability to combine the references, MPEP 2143.01III states the "fact that references can be combined or modified does

not render the resultant combination obvious unless the prior art also suggests the *desirability* of the combination." (Emphasis added). Neither of these disparate references suggest such desirability. As the Examiner indicated, "Rosenstein does not explicitly disclose modifying behavior of at least one of the plurality of physicians in the healthcare practice for management of ancillary medical costs responsive to the *data gathered* in the tangible computer medium [from each of the plurality of *physicians* in the Healthcare Practice participating in the insurance network]." Nor does Leet provide such desirability.

Applicants respectfully wish to point out that the teachings of estimating the cost of treating a patient with a given drug or combination of drugs (Leet, col. 15, lines 11-28) or displaying comparative costs (Leet, col. 3, lines 11-28), as set forth by the Examiner as being taught by Leet, would be obtained by *gathering patient-* and *disease-specific* data, i.e., changing medical information, side effects encountered, and patterns of disease resistance, and success of those treatments (col. 3, lines 10-40, and Fig. 2); and therefore, is not a teaching with respect to modifying such behavior responsive to *gathering data* from (on) the *physicians* in the Healthcare Practice participating in the insurance network.

Correspondingly, there is no motivation or suggestion to combine such disparate teachings in these cited documents to somehow build the claimed embodiments of the present invention, as each of these cited documents alone, and in combination, fail to provide any explicit or inherent motivation to combine references, fail to teach or suggest how to solve the problems solved by Applicants, and do not provide such teachings such that one skilled in the art would be provided sufficient information to combine their respective teachings to build the claimed embodiments of the present invention. As such, and for the reasons described above, persons of ordinary skill in the art who endeavor to solve the problems recognized by Applicants, would *not* be motivated to seek out or combine the teachings of the cited patent documents. Therefore, Applicants respectfully submit that the claimed embodiments of the present invention are novel, non-obvious, and define over Rosenstein and Leet.

No Reasonable Expectation of Success.

The Examiner has also not met the second element of a *prima facie* case for obviousness because there must be, and there is not in this present case, a reasonable expectation of success.

Clearly, from the discussion above, and a quick examination of the cited documents, one skilled in the art would realize that extensive modification of the teachings of the patent documents cited by the Examiner would be necessary to produce the Applicants' present claimed invention, namely, an improved or enhanced method of collecting fees for managing and/or optimizing profitability of a Healthcare Practice participating in an insurance network. Instead, the combination, as suggested above, would result in a hospital management system. Without a recognition of the source of the problems identified and addressed by the Applicants, Rosenstein and Leet, alone or in combination, simply could not know, and therefore could not describe, what to change in order to solve such problems.

Therefore, the second element of a *prima facie* case of obviousness has not been satisfied, and for this reason as well, the claimed invention is not obvious and defines over the cited art.

The Cited Patent Documents Fail to Teach or Suggest All the Claim Limitations.

Finally, the Applicants respectfully submit that the Examiner has not met the third element of a *prima facie* case for obviousness, which requires all claimed features be taught or suggested. In this case, as set forth above, the Examiner takes the position that Rosenstein in view of Leet shows all of the elements. Applicants respectfully submit that this simply is not true. First, citing Rosenstein, page 1, para. 1, the Examiner states that Rosenstein teaches "a method of collecting fees for managing and optimizing the profitability of a plurality of physicians in a healthcare practice participating in an insurance network" (Claim 1); "a method of collecting fees for managing a plurality of physicians in a healthcare practice participating in an insurance network" (Claim 8); and "a method of collecting fees for managing and optimizing the profitability of an insurance network having a plurality of physicians in a healthcare practice participating therein" (Claim 13). Applicants have been unable to find any reference to a method of *collecting fees* or optimizing the profitability of a plurality of physicians in a *Healthcare Practice participating in an insurance network*. Rather, Rosenstein is directed to various strategies that administrators in a closed, in-patient (hospital) system will be looking at to reduce health care costs. See Rosenstein, page 1, para. 1, and page 4, para. 5.

More particularly, regarding independent Claims 1, 8, and 13, Rosenstein or Leet, alone or in combination, do not disclose, teach, or suggest "establishing a relationships between a

Healthcare Consultation Group and [a] healthcare practice participating in [an] insurance network..., " as premised by the Examiner (citing Rosenstein (E) page 1, paras. 6-8). Applicants were unable to locate any mention in Rosenstein of either a "Healthcare Consulting Group" or working with any outside entity to make changes; but only the "routes hospitals may pursue" and the "incentives [hospital] administrators may encounter." See Rosenstein, page 2, para. 3. Nor does Rosenstein or Leet, alone or in combination, disclose, teach, or suggest "funding an incentive pool," as featured in Claims 1 and 8; or "paying funds from the funded incentive pool..." or "establishing a plan to pay funds from the funded incentive pool..." as featured in Claims 1 and 8, respectively. Although the Examiner cites Rosenstein (E), page 1, para. 6, as disclosing "funding an incentive pool," and Rosenstein (E), page 3, paras. 4-9, as disclosing "paying funds" or "establishing a plan to pay funds," "from the funded incentive pool...", " Applicants were unable to locate any mention in Rosenstein of either feature. There is simply no mention of "funding an incentive pool" nor either "paying funds" or "establishing a plan to pay funds" therefrom.

Nor does Rosenstein or Leet, alone or in combination, disclose, teach, or suggest "gathering data in a tangible computer medium from each of a plurality of physicians in the Healthcare Practice participating in the insurance network regarding management of ancillary medical costs," or "modifying behavior of at least one of the plurality of physicians in the healthcare practice for management of the ancillary medical costs responsive to the data gathered in the tangible computer medium," as featured in Claims 1, 8, and 13. Although the Examiner cites Rosenstein (E), page 1, paras. 6-10, as disclosing "gathering data in [a] tangible computer medium..." Applicants were unable to locate any mention in Rosenstein of such feature. There is simply no mention of using a computer to "gather" or aggregate ancillary medical cost data on physicians or physician groups. The Examiner further cited Leet, col. 15, lines 11-28, as disclosing modifying the physician behavior "responsive to the data gathered [regarding physician management of ancillary medical costs]." Applicants respectfully wish to point out that the teachings of estimating the cost of treating a patient with a given drug or combination of drugs (Leet, col. 15, lines 11-28) or displaying comparative costs (Leet, col. 3, lines 11-28), as set forth by the Examiner as being taught by Leet, would be obtained by *gathering patient-* and *disease-specific* data, i.e., changing medical information, side effects encountered, and patterns

of disease resistance, and success of those treatments (col. 3, lines 10-40, and Fig. 2); and therefore, is not a teaching with respect to modifying such behavior responsive to *gathering data* from (on) the *physicians* in the healthcare practice participating in the insurance network.

Further, neither Rosenstein nor Leet, alone or in combination, disclose, teach, or suggest "distributing predetermined percentages of savings attributed to the modifying behavior of the plurality of physicians ancillary medical cost management," as featured in Claim 1, doing so "if the ancillary medical costs decrease to the preselected level over the preselected period of time," as featured in Claim 8, or doing so "to at least one of the insurance network and the healthcare management consultation group when the ancillary medical costs decrease to a preselected level over a preselected period of time," as featured in Claim 13. Although the Examiner cites Rosenstein (E), page 2, paras. 4-10; page 3, paras. 4-9; and page 3, paras. 4-9, respectively, as "distributing predetermined percentages of savings attributed to the modifying behavior of the plurality of physicians..." Applicants were unable to locate either feature variation in Rosenstein. Rosenstein does not disclose a measurement system for "savings" through cost-effective care, or "predetermined percentages" for distribution.

Accordingly, as a proper *prima facie* case of obviousness has not been shown for the independent claims, Claims 1, 8, and 13, including a lack of motivation combine reference teachings and missing elements, Claims 1-20 have been shown to be nonobvious and define over the cited documents. The dependent Claims 2-7, 9-12, and 14-20, individually further have independent novelty and are nonobvious, as well.

Regarding Claims 2, 10, and 15, Applicants were unable to find what portions of the cited passages that Examiner identifies as "dividing the savings into selected percentages between at least two of the healthcare consultation group, the healthcare practice, and the insurance network and distributing the savings." Applicants do not know what entities the Examiner identifies in Rosenstein to constitute the "healthcare consultation group," "healthcare practice," or "insurance network," much less distribution of unused funds thereto. Further, nowhere in the text does Rosenstein disclose, teach, or suggest a "measurement" or "distribution system" for "savings". The text does not disclose, teach, or suggest any "preselected levels" or "predetermined percentages" or splits for the savings to be distributed to any party. Although Rosenstein does

mention “Shared Financial Risk,” where “the most effective strategy for insuring appropriate cost-effective behavior is to directly align physician incentives with hospital or managed care incentives...[so] physicians share directly in the rewards,” Rosenstein, page 2, para. 8, as is evident from this passage, Rosenstein does not disclose a method for distributing any predetermined percentages of saving.

Regarding Claims 3, 11, and 16, Applicants were unable to find what portions of the cited passages the Examiner identifies as “teaching collecting no fee by a Healthcare Consultation Group if the Healthcare Practice does not reduce the ancillary medical costs to the preselected level over the predetermined period of time.” Again, nowhere in the text does Rosenstein disclose, teach, or suggest a “measurement” or “distribution system” for “savings in ancillary medical costs.” The text does not disclose, teach, or suggest any “preselected levels” or “predetermined percentages” or splits for the savings to be distributed to any party. As such, if the “predetermined percentages” or “preselected levels” are not determined for any party, then fees cannot be defined, including “no fee” or zero percent. Finally, nowhere in the text does Rosenstein disclose, teach, or suggest a “Healthcare Consultation Group,” much less one working for free.

Regarding Claims 4 and 17, Applicants were unable to find what portions of the cited passages the Examiner identifies as teaching a disproportionate distribution of predetermined savings, or as teaching a Healthcare Consultation Group funding an incentive pool (Claim 4). First, Rosenstein does not disclose, teach, or suggest any kind of a relationship a “Healthcare Consultation Group,” much less funding an incentive pool. Further, nowhere in the cited text does Rosenstein disclose, teach, or suggest a “measurement” or “distribution system” for “savings”; nor any “preselected levels” for “predetermined percentages” or splits for the savings to be distributed to any party, much less the specific combinations of comparative party-distribution percentages identified in the claims. Although Rosenstein does mention “Shared Financial Risk,” where “the most effective strategy for insuring appropriate cost-effective behavior is to directly align physician incentives with hospital or managed care incentives...[so] physicians share directly in the rewards,” Rosenstein, page 2, para. 8, as is evident from this passage, Rosenstein does not disclose, teach, or suggest a method for distributing the predetermined percentages of the savings, much less as uniquely featured in the claims.

Regarding Claims 5, 11, and 18, Applicants were unable to find what portions of the cited passages the Examiner identifies as teaching a billing fee structure provided from a healthcare consultation group much less one where savings are calculated by subtracting current ancillary medical costs from a predetermined baseline or cost value. Again, as with respect to Claim 4, the cited text does not disclose, teach, or suggest any “preselected levels” for “predetermined percentages” or splits for the savings to be distributed to any party.

Regarding Claims 6 and 19, Applicants were unable to find what portions of the cited passages the Examiner identifies as teaching a fee structure calculated by multiplying a predetermined percentage of ancillary cost savings by a number of patients participating in a Healthcare Practice. Again, as with respect to Claim 4, the cited text does not disclose, teach, or suggest any “preselected levels” for “predetermined percentages” or splits for the savings to be distributed to any party. Further, Rosenstein is only applicable to a hospital or closed healthcare system environment, not a “Healthcare Practice” participating in the insurance network. *See* Rosenstein, page 2, para. 3 (stating that “[i]n this article, we suggest routes hospitals may pursue....”).

Regarding Claims 7, 12, and 20, Applicants were unable to find what portions of the cited passages the Examiner is referring to in support of the rejection regarding ancillary medical costs applicable to a Healthcare Practice participating in insurance network. Although Rosenstein mentions healthcare costs, Rosenstein only discloses/describes those healthcare costs applicable to a hospital or closed healthcare system environment. *See* Rosenstein, page 1, para. 1.

Regarding Claims 9 and 14, Applicants were unable to find what portions of the cited passages the Examiner is referring to in support of the rejection. Although arguably Rosenstein mentions that “efforts are now underway to apply these [hospital] utilization controls and reimbursement limitations more directly to the physician sector” (Rosenstein, page 2, para. 1), which are outlined elsewhere (Rosenstein, page 1, para. 3); and arguably introduces “Other Financial Incentives” to changing physician behavior by offering, “Equipment purchases, office space, marketing assistance or other services...as amenities for providing more cost-efficient care” (Rosenstein, page 2, para. 9). Nowhere in the cited text does Rosenstein disclose, teach, or suggest an “incentive pool” or “funding” mechanisms; “measures,” a “measurement system,” or

any “preselected levels” or “periods” for cost-effective care; acting upon recommendations of a Healthcare Consultation Group (Claim 9); or any kind of monies to be paid to an insurance network (Claim 14), much less doing so when modified medical management practices do not decrease ancillary medical costs.

Regarding Claim 12, citing Leet, col. 18, lines 49-67, the Examiner premises that Leet discloses to a method wherein “each of the respective predetermined percentages of savings distributed to the Healthcare Consultation Group and the Healthcare Practice are greater than the predetermined percentage of the savings distributed to the insurance network.” Applicants respectfully submit that when one expands the citation to complete the paragraph (Leet, col. 18, line 49 - col. 19, line 13), one can see this premise is incorrect because the “pharmacy costs” gathered are *not* the aggregate costs for the practice or physician, but those for a unique formula to rank medications to treat a given condition (Leet, col. 23, lines 7-8). The data sought in the ranking of medications is: “cost of medication per unit,” average “cost of administration by nursing personnel,” and “cost of a dispensing pharmacist (average time per pill/unit).” *See* Leet, col. 23, lines 11-18. Further, the formula used does not have a resulting unit of measure, because it adds both a time component (“Average times drug administered per day”) and cost components. *See* Leet, col. 23, line 19. Nowhere in the formulas are “savings” determined, “predetermined percentages of savings” computed for distribution, or are “Healthcare Consultation Groups” disclosed, taught, or suggested. Thus, Leet does not teach what the Examiner premises. Further, for the reasons indicated above and those described previously, there would be no motivation to combine Leet with Rosenstein as the combination would not achieve the features of Claim 12.

If the Examiner maintains the above rejections, the Applicants respectfully request the Examiner to specifically identify the structure or the structure of affected by the described steps which the Examiner equates to the above noted missing elements. Applicants respectfully submit that failure to do so by the Examiner would make this action improper.

Long Felt Need and Failure of Others.

In addition to the reasons provided above, Applicants also submit that there has been a long felt need to recognize the source of the problems and for a solution to the problems identified and addressed by the Applicants, especially in terms of managing and optimizing profitability of the physicians in a healthcare practice participating in an insurance network by modifying the behavior of a physician for management of ancillary medical costs. *See, e.g.*, Rule 132 Declaration of Charles C. Lewis, Armando Fuentes, or Richard G. Fiscella, para. 4d-4e, filed on Feb. 10, 2006 (providing evidentiary support). The Background section of the Application, pp. 1-8, objectively describes attempts by those skilled in the art to analyze the healthcare industry to attempt to satisfy the long felt need. *Id.* This includes use of an office manager to organize and manage medical treatment information in a manner which is preferred by an insurance network, and includes comparing healthcare provider performance to enhance competitiveness. Notably (and quite expectedly because Rosenstein dealt with closed-inpatient systems and Leet dealt with demographically enhanced disease management), neither Rosenstein nor Leet recognize ancillary medical costs for a Healthcare Practice as a source of their problems, and thus, have also not provided an effective solution. Correspondingly, others have not failed to solve the long-felt need due to lack of interest or lack of appreciation of the potential for marketability of the claimed invention, Claims 1-20, but rather due to want of technical know-how.

Accordingly, as a proper *prima facie* case of obviousness has not been shown, and even if it had been shown, has been rebutted, Claims 1-20 have been shown to be nonobvious and define over the cited art.

In commenting upon the references and in order to facilitate a better understanding of the differences that are expressed in the claims, certain details of distinction between the references and the present invention have been mentioned, even though such differences do not appear in all of the claims. It is not intended by mentioning any such unclaimed distinctions or making any amendments herein to create any implied limitations in the claims. Not all of the distinctions between the cited patent documents and Applicants' present invention have been made by Applicants. For the foregoing reasons, Applicants reserve the right to submit additional evidence

showing the distinctions between Applicants' invention to be novel and nonobvious in view of the cited patent documents.

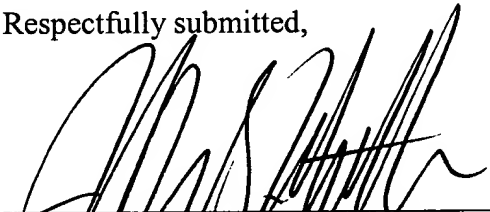
The foregoing remarks are intended to assist the Examiner in re-examining the application and in the course of explanation may employ shortened or more specific or variant descriptions of some of the claim language. Such descriptions are not intended to limit the scope of the claims; the actual claim language should be considered in each case. Furthermore, the remarks are not to be considered to be exhaustive of the facets of the invention that render it patentable, being only examples of certain advantageous features and differences.

CONCLUSION

In view of the above remarks Applicants submit that the claimed invention is in condition for allowance. As such, the issuance of a Notice of Allowance is respectfully requested.

Respectfully submitted,

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Changing Physician Behavior Is Tool to Reduce Health Care Costs

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Abstract (Document Summary)

Health care payers and the government have designed utilization controls on hospitals in order to reduce costs. Efforts are now under way to apply these same utilization controls and reimbursement limitations more directly to the physician sector. Physicians can have a significant financial impact on reducing non-reimbursable expenses if they are educated concerning the value of efficient utilization and resource consumption. The strategies that administrators can employ include: shared financial risk, other financial incentives, information sharing, physician profiling, and physician education. In initiating changes in physician behavior, administrators must recognize that they may encounter obstacles that include old incentives, traditionalism, impact on quality, and malpractice concerns.

Full Text (2390 words)

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- 1 Hospital administrators in the next decade will be looking at every avenue to reduce health care costs at the suggestion of the payers and patients. What is the role of physicians in such an effort? In the following article, the authors discuss the pros and cons of influencing physician practice patterns to cut excesses and improve quality of care. They summarize the "influencing strategies" and explain why some of them will create opposition among practitioners.
- 2 Today's health care environment is plagued by concerns about continued escalation in costs and spending. In an effort to reduce some of the financial burden, health care payers have reacted by transferring their risk to the provider, particularly the hospital.
- 3 To promote greater efficiency in the process of delivery, payers and the government have designed utilization controls emphasizing necessity of treatment and appropriate levels of care along with direct reimbursement limitations in the forms of capitation, per-diem or per-diagnosis payments and other forms of discounted contractual care.
- 4 But while these controls are intended to have a primary effect on hospital-related services--40% of the health care dollar--they have had only a small cost-savings effect.
- 5 In reality, they merely curb the trend in cost escalation by shifting many of the costs to the outpatient sector. One of the difficulties associated with these proposals is the diametrically opposed economic incentives evoked among hospitals, managed care organizations and physicians. (See Table 1, page 15).

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Table 2: Influencing Physician Behavior

Pros

New Incentive Profit Sharing

Organizational Survival Reaction/Interaction

Impact on Quality Quality=Quantity

Information Sharing Follow Peer Standards

Objective Performance Physician Education

Provider Interaction

Cons

Old Incentives Fee-for-Services vs. Other

Traditionalism Inertia/Rationalization Reduce Hospital Overhead

Impact on Quality Quality=Efficiency

Malpractice Concerns Defensive Reaction

Science vs. Economics Qualitative Judgments

Bad Apple Approach Remove the Bad

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- 1 Efforts are now underway to apply these same utilization controls and reimbursement limitations more directly to the physician sector, which has been only indirectly impacted by many of these changes.
- 2 On the inpatient side, physician activities may be influenced by aggressive utilization monitors and managed care priorities. But there is little economic incentive for them to change their practice patterns if they continue to be reimbursed under a fee-for-service reimbursement system. On the outpatient side, the move to transfer more medical care to that sector only favors the traditional autonomy of physician practices.
- 3 In this article, we suggest routes hospitals may pursue in dealing with these changes, analyzing the potential obstacles and incentives administrators may encounter in attempting to influence physician behavior.

Old Story, New Solution

- 4 It's no news that hospitals operating under the financial risks imposed by more stringent reimbursement policies are having a difficult time making ends meet.
- 5 Depending on their payer mix, most institutions are lucky to collect 50 to 60 cents on every dollar charged. With contractual deductions in the 40 to 50% range, it is now estimated that more than 50% of hospitals run at an operational loss.
- 6 In an effort to maintain a positive bottom line, administrators may try to increase revenues by increasing price or volume, but under today's reimbursement structure, this will have limited effect. They may also attempt to reduce expenses by limiting overhead and streamlining operations. But the greatest effect will be achieved by improving efficiencies in actual health care delivery.

Behavior Calls For Strategy

- 7 Since physicians are responsible for admission, discharge and ordering services for most of the reimbursement categories, they can have a significant financial impact on reducing non-reimbursable expenses if they are educated concerning the value of efficient utilization and resource consumption. The strategies that administrators can employ include:
- 8 **Shared Financial Risk:** The most effective strategy for insuring appropriate cost-effective behavior is to directly align physician incentives with hospital or managed care incentives. This works best when physicians work as employees of the organization as typified by the Kaiser or other staff model health maintenance organizations (HMOs). When MDs are indoctrinated into a capitated system, cost-conscious utilization of resources results because both the institution and the physician share directly in the rewards.
- 9 **Other Financial Incentives:** Tying performance to other types of benefits may also a change in practice patterns. Equipment purchases (lasers, endoscopes, etc.), office space, marketing assistance or other services may be offered as amenities for providing more cost-efficient care.
- 10 In the hospital sector, for example, those departments that perform more efficiently may be given a greater percentage from the capital budget, new equipment or other departmental improvements.
- 11 **Information Sharing:** One of the initial problems we face in approaching physicians about practice behavior is the "information void" created by the autonomous nature of their practice.
- 12 By presenting MDs with information that allows them to compare their practice patterns with those of their peers, we can stimulate changes in behavior. There's safety and confidence in following the standards established by their colleagues.
- 13 The hospital, depending upon its payer mix, gains financially from a reduction in non-reimbursable costs of services. The physician gains by quality of care improvement recognized by practicing at the standards established by their peers.
- 14 **Physician Profiling:** We must note that many outside agencies are already collecting and analyzing data in an effort to scrutinize providers in regard to the necessity, appropriateness, efficiency and outcomes of their interventions.
- 15 Payers are "selectively contracting" with "more efficient" providers who are perceived as offering a higher service value based on both cost and utilization data. Some proponents of these systems have suggested that "economic credentialing" will be the path of the future.
- 16 In response to external demands for more cost-efficient care, will health care institutions begin to tie cost and utilization data into the credentialing process, offering privileges only to those providers who demonstrate more desirable patterns of care? Some have already done so.
- 17 Given this condition, it may be in the best interest of the physician to maintain internal control of the system by promoting internal cost-effective activity, rather than being forced to respond to externally driven demands.

- 1 Physician Education: From our viewpoint, physician education is the key to promoting cost-effective changes in practice behavior. After stimulating interest with the information sharing process, the next step is to provide MDs with viable alternatives for improving care.
- 2 The educational format should be conducted at several levels. First, there must be a basic educational seminar designed to familiarize the physician with the economic constraints and ramifications of medical practice in today's health care environment.
- 3 Second, medical staff leaders and other key medical representatives must be solicited to help analyze information on health care activities by physician, by service, by diagnosis or by procedure.
- 4 This effort is designed to isolate unwanted variances and to suggest alternatives for improvement. The most crucial component of the entire process is to disseminate information back to the medical staff to encourage input and suggestions for change.
- 5 The educational process is a particularly useful tool to share cost information with physicians. Several studies have documented physician unfamiliarity or confusion about the costs of medical tests and procedures. Other research has shown that efforts aimed at educating physicians about cost-containment procedures can have a definite impact on lowering the costs of medical care.

Steps Raise Pros, Cons

- 6 Physicians have always practiced autonomously under the belief that only those who have comparable medical training should be involved in decisions about care.
- 7 Hospitals and other outside agencies are often perceived as mingling or interfering with patient care, and at times find themselves in adversarial relationships with physicians. This is particularly evident when institutions try to influence medical decisions based on a concern for hospital economics that may be construed as being in direct conflict with physician concerns about quality care.
- 8 In initiating changes in physician behavior, administrators must recognize that they may encounter obstacles (see Table 2, page 16) that include:
- 9 Old Incentives: Despite significant changes in hospital reimbursement philosophy, physicians continue to be reimbursed on a modified fee-for-service structure that provides little incentive for cost-efficient care. Under the structure, they are financially rewarded for services provided.
- 10 Traditionalism: Resistance to change can come from inertia, reluctance or entrenchment in traditional practice standards, or it can rise from the perception that top-heavy administration must first do their part by demonstrating their own abilities to streamline operations and improve performance efficiencies.
- 11 Impact on Quality: Some physicians believe that reducing the number of tests they order will have a negative impact on patient care. Trained with the idea that quality equals quantity, MDs frequently believe that they are obligated--if not entitled--to use all the resources at their disposal to make a diagnosis.
- 12 In an article entitled, "Our Stubborn Quest for Diagnostic Certainty: A Cause for Excessive Testing" in the June 1, 1989, issue of the New England Journal of Medicine, author J. Kassirer calls this our never ending quest for diagnostic certainty.
- 13 However, we must also pay mind to the caveat "physician do no harm." Recent studies have shown that many of the tests we perform may not be clinically necessary and may cause unwanted adverse effects. In fact, it has now become clear that efficient utilization of health care resources actually improves overall quality of care. The hospital benefits in two ways: improved quality of patient care and the economic stimuli of avoiding additional costs accrued by treating avoidable patient complications.
- 14 Malpractice Concerns: We cannot argue that certain tests are ordered specifically for the purpose of protecting oneself from potential future malpractice reprisals. But judicious, well-documented medical care that conforms to community standards is the best defense against such accusations.
- 15 Science Versus Economics: Another argument raised by physicians asked to modify their practice behavior is the validity of applying objective economic criteria to an institution based on a subjective behavioral science. This interpretation may be true, but we believe that objective measurement of physician patient care activities can be used to mold a subjective science into a more effective modality.
- 16 The Bad Apple Approach: Some physicians may feel that the overall intention of data accumulation, intensive monitoring and external scrutiny is designed solely for the purpose of weeding out the bad apples.
- 17 While some organizations may have this as their primary intention, our goal is to push the entire system toward a greater efficiency. D. Berwick, author of "Continuous Improvement as an Ideal in Health Care," published in the Jan. 5, 1989, issue of the New England

Journal of Medicine, refers to this process as the theory of continuous improvement.

- 1 Physicians are more likely to take offense and offer resistance if they think that the purpose of information gathering is a witch hunt to eliminate colleagues who don't adhere to the institution's desired expectations. But everybody must work together to drive the system to a new level of performance.

Impact Worth the Effort

- 2 While these obstacles may present challenges to both hospital CEOs and physicians, changing practice patterns have important positive economic repercussions, however, that should inspire administrators to focus on them. They include:
- 3 New Incentives: As more care is delivered under managed care systems, MDs will assume more of the financial risks for patient care. Capitation, lumped payments, ambulatory DRGs and payments tied to necessity and outcome will have a significant impact on physician-related services. Rather than trying to treat each patient differently according to their financial class, we suggest treating all patients as efficiently as possible, which should lead to overall financial rewards.
- 4 Organizational Survival: Physicians are creatures of habit. They regard the hospital as their traditional workplace for providing inpatient care, and although they may be reluctant to admit it, they become perturbed when their patterns are disturbed.
- 5 If a hospital closes, the physicians would be forced to find a new workshop for inpatient care, not to mention the impact on disturbing their customary referral base.
- 6 Similarly for health maintenance organizations (HMOs) and preferred provider organizations (PPOs), if the physicians depend on one or two of these groups as a major source of patients, and the HMO folds, they suffer the consequences.
- 7 With hospital closures, mergers and organizational bankruptcy rising, physician behavior can play an important role in keeping these institutions financially stable.
- 8 Impact on Quality: We believe that cost-efficient care results in high quality care, and high quality care subsequently leads to efficient care. Programs that emphasize physician education following the principles of continuous improvement will ultimately foster the highest standards of quality care.
- 9 Information Sharing: "Information sharing" about practices between physicians is an important incentive as well as a strategy for administrators and physicians to focus on changing practice patterns.
- 10 It is up to physicians to maintain internal control of a system that is now being inundated by these external agencies who establish their own priorities for directing care. Lack of physician attention to this issue is a direct invitation for others to gain more power in this arena.
- 11 Objective Performance: While it is true that medicine is a qualitative science, quantitative input can be used to point out standards and variances in care that can be molded into an improved level of performance. Reducing physician variances in care promotes more cost-efficient utilizations of resources.
- 12 Provider Interaction: One final strategy appeals to the physician's obligation of trying to provide the best in overall patient care. As the health care dollar becomes an increasingly limited medical resource, only more efficient utilization of resources will prevent further rationing and allow health care services to continue to be available when needed.
- 13 As the health care crisis continues to unfold, it is imperative to win physician involvement in a process that eventually provides cost-effective, high-quality care.
- 14 Physicians must work together, with hospitals, managed care systems, and other health care organizations and take responsibility for developing systems that maximize efficiency in the utilization of health care resources.
- 15 Payers will benefit from a better value for their money. Providers will benefit from overall improvements in quality and efficiency. Patients will benefit from more appropriate allocation, utilization and access to health care resources.
- 16 The reality of creating a more efficient health care system is now within our reach. We are limited only by our creativity and dedication in working toward this goal.

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